UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/222,123	12/29/1998	ROBERT A. RAY	6328-21	3601

7590 08/02/2002

J. RODMAN STEELE, JR., ESQ.
AKERMAN, SENTERFITT & EIDSON, P.A.
222 LAKEVIEW AVENUE SUITE 400
POST OFFICE BOX 3188
WEST PALM BEACH, FL 33402-3188

EXAMINER	
CROSS, LATOYA I	
ART UNIT	PAPER NUMBER
1743	22

DATE MAILED: 08/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

HCT

Office Action Summary	Application No.	Applicant(s)	
	09/222,123	RAY ET AL	
	Examiner	Art Unit	
	LaToya I. Cross	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-21,24-27 and 29-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-21,24-27 and 29-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 12, 2002 has been entered. Claims 19-21, 24-27 and 29-42 are pending in the application.

Withdrawal of Rejections from Previous Office Action

- The rejection of claims 1, 4, 7, 8, 10, 19, 21, 22 and 24-26 under 35 USC 103 over Bahl et al '160 is withdrawn in view of Applicants' incorporation of polyvinyl alcohol as the collection pad material into the claims.
- The rejection of claims 5, 11, 12, 20 and 23 under 35 USC 103 over Bahl et al in view of Chandler '416 and the rejection of claims 2, 3, 6 and 9 under 35 USC 103 over Bahl et al in view of May et al '503 are withdrawn in view of Applicants' incorporation of polyvinyl alcohol as the collection pad material into the claims.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a

person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 19, 21, 24-27 and 29-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,609,160 to Bahl et al in view of US Patent 5,728,350 to Kinoshita et al.

Bahl et al '160 teach a fluid sample collection device comprising a plastic frame having a handle end (30, 40) and a collection end. The plastic frame is rigid enough to be held by the user, as in claims 25 and 26. The device contains an absorbent cotton (cellulosic) pad (50) for collecting the sample. There are openings (32, 42) through the collection end of the device such that the absorbent pad is exposed and capable of collecting the sample. The device also contains an additional opening (28), which allows the oral sample to be extracted during

centrifugation. The openings may allow a portion of the absorbent pad to be removed from the device, as recited in claims 19, 21, 33 and 34. At col. 4, lines 8-14, Bahl et al '160 disclose that a portion of the absorbent pad is treated with a chemical indicator (dye) such that when sufficient fluid is taken up by the pad, a change in color occurs. Also provided is a package for return of the sample by mail, and an identification card (90) containing information for identifying the sample, as recited in claims 19 and 24. See figures 1 and 10. The collection pad is made of pure cotton with no chemicals added to it (col. 3, lines 40-41). The collection pad may be coated with Bovine Serum Albumin under the aperture, as in claims 35 and 36 (col. 4, lines 26-34).

Bahl et al '160 fail to teach polyvinyl alcohol as the absorbent material, as recited in claims 19 and 27-32.

Kinoshita et al '350 teaches a test kit having an absorbent sample receiving part on a support material. The sample receiving part is made of water absorbing fibrous material, such as polyvinyl alcohol. See col. 3, lines 46-63. Kinoshita et al '350 teach that polyvinyl alcohol materials are preferred because they have an excellent effect of thickening the liquid sample when the sample is absorbed. Thus, sample is retained more firmly and is difficult to remove. (col. 4, lines 1-5). It would have been obvious to one of ordinary skill in the art to use the polyvinyl alcohol material disclosed by Kinoshita et al '350 in the Bahl et al device to provide enhanced absorbency for the sample. With respect to the pore size of the polyvinyl alcohol material, the ordinarily skilled artisan would have been able to choose a pore size that allows sufficient absorption when used.

Claims 40-41 are directed to urine as the sample material; however, such limitations do not impart patentability to the claims since they are directed to the materials worked on by the

apparatus. The apparatus may be used with any sample material. See MPEP 2115 citing *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Therefore, for the reasons above, Applicants' claimed invention is deemed obvious, within the meaning of 35 USC 103 in view of the teachings of Bahl et al and Kinoshita et al.

6. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bahl et al in view of Kinoshita et al as applied to claims 19, 21, 24-27 and 29-42 above, and further in view of US Patent 5,976,895 to Cipkowski.

With respect to claim 20, neither Bahl et al nor Kinoshita et al teach a collection cup.

Cipkowski teaches a device for collecting and shipping body fluid samples. The device includes a cup (11). Test strips are inserted into the cup to contact the sample. It would have been obvious to one of ordinary skill in the art to use a cup with the collection strips of Bahl et al to deliver the sample to the test strip in a controlled manner and avoid spillage or waste of the sample.

For the reasons above, Applicants' invention is deemed obvious, in view of Bahl et al, Kinoshita et al and Cipkowski.

Response to Arguments

7. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

LIC

July 25, 2002

Jill Warden
Supervisory Patent Examiner
Technology Center 1700